IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT GENERAL-CAUSATION TESTIMONY OF DONALD R. OSTERGARD, M.D.

Donald R. Ostergard, M.D. seeks to offer various opinions regarding the ability of Prolene, Gynemesh PS, and Prolift products to cause the injuries alleged by the several plaintiffs in Wave 3 of this litigation.[1] But Dr. Ostergard's recent testimony shows that many of these opinions are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), including:

- **Opinions regarding safer alternative designs.** Dr. Ostergard states in his report that Gynemesh PS has detrimental qualities and/or a higher rate of adverse events compared to Polyform, Popmesh, Pelvitex, and Timesh. Yet the scientific literature Dr. Ostergard relies on does not support these opinions. And not only did Dr. Ostergard admit in his deposition that he is not aware of any other studies that would support these opinions, he testified that he is not opining that these meshes are suitable alternative meshes to Gynemesh PS. The Court should therefore exclude these opinions.

[1] Dr. Ostergard is designated as a general-causation expert for three cases involving TVT products (*see* Ex. A, List of Cases to which Motion to Exclude the General-Causation Testimony of Donald R. Ostergard, M.D. Applies), but he does not offer opinions about these products and therefore his general-causation opinions should not apply to these cases despite Plaintiffs' designation.

- **Opinions regarding carcinogenicity of polypropylene.** Dr. Ostergard admits he cannot make a causal connection—or even an association—between polypropylene and cancer. Accordingly, his cancer-related opinions should be excluded as unreliable. Dr. Ostergard's carcinogenicity opinions should be excluded from cases in which cancer is not alleged on the additional grounds that they are irrelevant and therefore inadmissible.

- **Opinions relating to warning adequacy and regulatory matters, infection, and corporate knowledge.** This Court has repeatedly excluded this opinion testimony in other cases based upon Dr. Ostergard's lack of qualifications, the lack of relevance of these opinions, and because these opinions will not assist the trier of fact. The same holds true here.

As more fully explained below, Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) ask that these opinions be excluded.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Ostergard's safer-alternatives opinions are not reliable because they are not supported by sufficient facts or data.

Expert testimony is only admissible under Rule 702 if it is "based upon sufficient facts or data"—*i.e.*, if it "rests on a reliable foundation." *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014) (citing FED. R. EVID. 702; *Daubert*, 509 U.S. at 597) (internal quotation marks omitted). An expert's opinion does not rest on a reliable foundation if the study or studies the expert relies upon do not support the expert's opinion. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 524 (S.D.W. Va. 2014).

That is precisely the case here as to Dr. Ostergard's safer-alternatives opinion. He proposes to testify that there are safer alternatives to Gynemesh PS, specifically discussing in his report four other meshes that he asserts have favorable characteristics: Polyform, Popmesh, Pelvitex, and Timesh. *See* Ex. B, Ostergard Report at 3-4, ¶¶ 7(k), (l). First, he states that,

"[b]ecause of the high rate of adverse events," lighter-weight meshes, such as Polyform and Popmesh, "are preferred to reduce complications." *Id*. at 3-4, ¶ 7(k). In support, he cites a 2009 article authored by Dr. Keisha Jones and others. *Id*. at 4. But these authors found that the four lighter-weight meshes that Dr. Ostergard discussed in his report were subject to "irreversible deformation at significantly lower loads." Ex. D, Keisha A. Jones, et al., *Tensile properties of commonly used prolapse meshes*, 20 INT'L UROGYNECOLOGY J. 847, 847 (2009) (Jones (2009)). Accordingly, far from concluding that the meshes identified by Dr. Ostergard are preferred to reduce complications, these authors concluded that they are "inferior" from a biomechanical perspective because of their "susceptibility to permanent elongation and, hence, *anatomical failure*." *Id*. at 852 (emphasis added). This study therefore does not support Dr. Ostergard's opinion that these meshes are preferable to Gynemesh PS and therefore this opinion is not reliable.

Dr. Ostergard also proposes to testify that "Gynecare Gynemesh PS is also a high stiffness mesh when compared to Polyform, Pelvitex and Timesh. This is a detrimental quality since increased mesh stiffness has been correlated with an increased erosion rate." Ex. B, Ostergard Report at 4, ¶ 7(l). In support, he cites only two articles: the Jones 2009 article discussed above and a 2006 article by Dr. M. Huebner. *Id*. Neither supports this opinion.

While the Jones article's authors noted that "mesh stiffness has been one of the parameters that have been *hypothesized to contribute to exposures or erosions*," their study did not purport to find a correlation between the two—nor could it have, given that it was merely a study of biomechanical properties of the mesh *ex vivo*. Ex. D, Jones (2009) at 850 (emphasis added). And, as noted, far from concluding that the relatively higher stiffness observed was a "detrimental quality" (Ex. B, Ostergard Report at 4, ¶ 7(l)), the authors concluded that the lower

stiffness of the newer meshes was the characteristic that caused "irreversible deformation at significantly lower loads," leading to "anatomical failure" (Ex. D, Jones (2009) at 847, 852). Accordingly, while the Jones study might support Dr. Ostergard's statement that Gynemesh is stiffer than Polyform, Pelvitex, and Timesh, it does not support his assertion that Gynemesh is therefore inferior.

Nor does the Huebner article support Dr. Ostergard's opinion that Gynemesh's stiffness renders it inferior to Polyform, Pelvitex, or Timesh in terms of erosion rates. Indeed, the only relevant discussion of this point in the Huebner article uses a Gynecare mesh product as an example of a product that has "*outstanding success . . . in terms of graft erosion*," in part because of its "flexibility or low stiffness . . . ." Ex. E, M. Huebner, et al., *The use of graft materials in vaginal pelvic floor surgery*, 92 INT'L J. GYNECOLOGY &OBSTETRICS 279, 280 (2006) (emphasis added). This is because, as the authors discuss, the meshes whose stiffness increases the likelihood of erosion are *microporous* meshes, such as Gore-Tex. *Id*. The preferred meshes, according to these authors, are *macroporous* meshes like those used in Ethicon's Gynecare TVT and other products. *Id*. The Huebner article does not offer any comparison of Gynemesh stiffness to that of Polyform, Pelvitex, or Timex—indeed, it does not even mention the latter products. *See generally id*. Nor does it discuss any studies that compared the stiffness of Gynemesh to the stiffness of meshes like those identified by Dr. Ostergard, let alone any studies that concluded that the differences in stiffness were correlated with an increased erosion rate. *See generally id*.

Dr. Ostergard did not cite any articles other than Jones 2009 and Huebner 2006 as supporting his opinions regarding alternative meshes. And he identified no additional studies that would support his opinions in his deposition. Dr. Ostergard admitted at his deposition that he does not know if any of the alternative meshes he named in his report have been studied in

patients with prolapse in any randomized clinical trials. *See* Ex. C, Ostergard 3/9/16 Dep. Tr. 118:16-119:19. He testified that he is not aware of any studies comparing any of these meshes to Gynemesh PS. *Id*. at 119:9-120:12. In fact, he could not recall any studies of women who had undergone implantation of these meshes for treatment of pelvic organ prolapse. *Id*. at 119:5-8, 120:14-17; *see also id*. at 120:22-121:1 ("Q. And you have seen no demonstrable benefit to those meshes compared to Gynemesh PS in women, true? A. I don't think there are any publications on these other meshes."); *id*. at 121:13-17 (admitting he did not "investigate the regulatory status of them for the treatment of pelvic organ prolapse in women in this country"). Consistent with these admissions, Dr. Ostergard testified that he is not opining that these meshes are "suitable alternative meshes to Gynemesh PS." *Id*. at 120:18-21. If they are not suitable alternatives to the Gynemesh PS, then his testimony in this regard is not only unreliable, it is also irrelevant.

Based on these admissions, Dr. Ostergard should be precluded from offering opinions regarding safer alternatives. The opinions stated in his report as to these alternatives (*see* Ex. B, Ostergard Report at 3-4, ¶¶ 7(k), (l)) should therefore be excluded as unreliable and irrelevant.

II. Dr. Ostergard's carcinogenicity opinions should be excluded.

The Court should exclude Dr. Ostergard's carcinogenicity opinions in all cases for three reasons. First, Dr. Ostergard does not discuss cancer, carcinogens, or neoplasms in his report. *See generally* Ex. B, Ostergard Report. At deposition, however, Dr. Ostergard testified about "two neoplasms that have been described with polypropylene mesh." Ex. C, Ostergard 3/9/16 Dep. Tr. 103:2-4. This is a "new opinion" not previously disclosed and should be excluded on that basis alone. *See, e.g.*, *Trevino v. Boston Scientific Corp.*, No. 2:13-CV-01617, 2016 WL 2939521, at *10 (S.D.W. Va. May 19, 2016) ("Rule 26 of the Federal Rules of Civil Procedure requires an expert report to contain 'a complete statement of all opinions the witness will express and the basis and reasons for them.'").

Second, his carcinogenicity opinions are excludable because they lack "sufficient facts or data." FED. R. EVID. 702. Indeed, Dr. Ostergard testified unequivocally that "there's no proof [polypropylene mesh] causes cancer." Ex. C, Ostergard 3/9/16 Dep. Tr. 103:8-9. When asked if he intended to testify at trial that Gynemesh PS causes cancer or sarcoma, Dr. Ostergard responded, "*I would never testify that it causes cancer*." *Id*. at 104:22-23 (emphasis added); *see also id*. at 104:25-105:6 (testifying that he did not think he included any such opinions in his report). He initially asserted that there was an association between polypropylene mesh and cancer. *See id*. at 103:9-10 ("It's just an association at this point."); *id.* at 104:23-24 ("All I could testify to is it has been found in association with cancer."); *id.* at 199:10-11 ("No causation has been established, only association."). But he was forced to admit on further questioning that an association has actually not been established because "there's only been one case reported." *Id*. at 199:12-20. These admissions establish that Dr. Ostergard should be precluded from offering cancer-related opinions in all cases—even those in which the plaintiff alleges that she developed cancer as a result of a mesh implant.

And lastly, in cases where cancer is not an alleged injury, the Court should exclude Dr. Ostergard's carcinogenicity opinions for the additional reason they are irrelevant. As the Court has held, "the mention of cancer in the context of [such a] case would, at a minimum, offend Federal Rule of Evidence 702 and confuse the jury on a matter with scant probative value." *Wise v. C.R. Bard, Inc*., No. 2:12-CV-01378, 2015 WL 521202, at *7 (S.D.W. Va. Feb. 7, 2015); *see also In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4536456, at *3 (S.D.W. Va. Aug. 30, 2016) (excluding Dr. Ostergard's general-causation opinions as to complications not alleged or experienced by any of the applicable plaintiffs).

Dr. Ostergard's testimony establishes that his carcinogenicity opinions should be excluded because Dr. Ostergard admits that he could not reliably opine that polypropylene is even associated with cancer, let alone that it can cause cancer. And these opinions are irrelevant in cases in which cancer is not alleged in any event.

III. Dr. Ostergard's infection opinions should be excluded as irrelevant.

An expert witness is only permitted to testify if his or her "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or *to determine a fact in issue*." *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied sub nom.* 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014) (citing FED. R. EVID. 702) (emphasis in original). Dr. Ostergard's opinions regarding mesh-related infections do not help determine a fact in issue, and are therefore irrelevant, in cases where the plaintiff has not alleged infection. *See, e.g.*, *In re: Ethicon*, 2016 WL 4536456, at *3 ("To the extent any of the plaintiffs for whom Dr. Ostergard is an expert did not experience infections, Dr. Ostergard's opinions on these topics are EXCLUDED.").

The cases to which Dr. Ostergard's general causation opinions ostensibly apply are listed in Exhibit A to the motion accompanying this memorandum. To the extent that any of these cases do not involve infection, Dr. Ostergard's infection opinions should be excluded in those cases. Those opinions include the following:

- "The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages." Ex. B, Ostergard Report at 2-3, ¶ 7(a).

- "With loss of PP due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence . . . which increases the inflammatory reaction and intensity of fibrosis." *Id*. at 3, ¶ 7(d).

- "Predominate infection/inflammation was noted in 2007 in explanted samples from Dr. Cosson's series of patients." *Id.* at 3, ¶ 7(g).

- "The large surface area promotes wicking of fluids and bacteria and is a 'bacterial super highway' which provides a safe haven for bacteria which attached themselves to the mesh during the insertion process." *Id*. at 3, ¶ 7(h).

- "The size of the mesh placed equates to a very large surface area with many places for bacteria to hide, protected from host defenses." *Id*. at 4, ¶ 8(a).

IV. Dr. Ostergard is not qualified to testify about FDA regulatory requirements or what warnings should be included in an IFU.

In the Court's recent rulings in this litigation, the Court held that, while an expert who is a clinical practitioner, such as a urologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., No. MDL 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (excluding such opinions of plaintiff's urology expert Jerry Blaivas, M.D.); *see also id.* (excluding expert testimony about product warnings, including testimony about the adequacy of the relevant Instructions for Use (IFU), from medical doctors who are not "expert[s] in the development of warning labels"). While Dr. Ostergard is an experienced obstetrician and gynecologist, he does not have additional expertise that would qualify him to offer opinions about what information should or should not be included in the IFU.[2] *See generally* Ex. B, Ostergard Report & Ex. A to same (Ostergard C.V.).

[2] Ethicon argued in its Wave 1 Memorandum in Support of Motion to Exclude General-Causation Testimony of Donald R. Ostergard, M.D. (and adopted this argument with its Wave 2 Notice of Adoption of its Wave 1 Motion), that Dr. Ostergard's warnings-related opinions should be excluded due to his lack of qualifications. *See* Dkt. 1997 at 11. The Court's ruling does not appear to address this argument, however. *See generally In re: Ethicon*, 2016 WL 4536456. Defendants accordingly renew it here and respectfully request that the Court's ruling on this motion apply to Defendants' Wave 1 and 2 motions as well.

Because Dr. Ostergard is not an expert in the development of warning labels, the Court should exclude the following proposed testimony:

- Dr. Ostergard's testimony that the Prolift IFU is "defective" because it does not say that the training recommended by Ethicon is "required." Ex. C, Ostergard 3/9/16 Dep. Tr. 147:3-10. Dr. Ostergard testified, "I am not aware of any regulatory standard [requiring that surgeons be trained on use of a device], but it does not mean that Ethicon or any other company can't go beyond and make sure that the physicians that are going to use their devices are adequately trained to put the devices in safely." *Id.* at 147:23-148:2.

- "Ethicon chose what information MD's needed to know in the Professional Education slides." Ex. B, Ostergard Report at 21, ¶ 16(e).

- "Ethicon chose what information patients needed to know." *Id.*, ¶ 16(f) (citing Prolift Patient Brochure).

- "Ethicon made no changes the Prolift IFU after 2008 FDA Communication." *Id.* at 22, ¶ 16(h).

- Testimony based on Dr. Ostergard's narrative review of corporate documents included in the section titled "Other Issues," to the extent that Dr. Ostergard proposes to testify about the relevance or implications of his review of these documents with respect to FDA regulations and whether Ethicon's product labels satisfy those regulations. *Id.* at 25-28, ¶¶ 18(a)-(tt).

V. Dr. Ostergard's opinions on Ethicon's intentions and narrative review of corporate documents are inadmissible.

The Court has held that it will "exclude state-of-mind and legal-conclusion expert testimony." *In re: Ethicon*, 2016 WL 4536456, at *4. These matters "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *In re Ethicon, Inc.*, 2014 WL 186872, at *6, *21. In *Huskey*, the Court also excluded expert opinions that offer "simply a narrative review of corporate documents," holding that such "opinions" are not helpful to the jury. 29 F. Supp. 3d at 706; *see also In re: Ethicon*, 2016 WL 4536456, at *5 (holding that the Court will not permit experts to "parrot[] facts found in corporate documents[,]" and cautioning "against introducing corporate evidence through expert witnesses"). The Court should do the same here and exclude any opinions of Dr. Ostergard (1) regarding Ethicon's knowledge,

state of mind, or other matters related to corporate conduct and ethics or (2) that are merely a narrative review of Ethicon's documents. This includes, but is not limited to, the following proposed testimony:

- Dr. Ostergard's statement, "It concerns me that Ethicon would deliberately not warn doctors about its knowledge of complications arising from implanting its Prolift, Prolift+M, Prolene, Gynemesh, or Gynemesh PS products. As [a] doctor, I must make decisions to benefit, and not to harm my patients. I need full and accurate information so that I can make those decisions and so that I can fully discuss benefits and risks with my patients. If I cannot rely on information provided by manufacturers, I cannot obtain full and complete consent from my patients and they could suffer harm as a result." Ex. B, Ostergard Report at 28, ¶ 19.

- Dr. Ostergard's testimony that the Prolift IFU is "defective" because it does not say that the training recommended by Ethicon is "required." Ex. C, Ostergard 3/9/16 Dep. Tr. 147:3-10. Dr. Ostergard testified, "I am not aware of any regulatory standard [requiring that surgeons be trained on use of a device], but it does not mean that Ethicon or any other company can't go beyond and make sure that the physicians that are going to use their devices are adequately trained to put the devices in safely." *Id.* at 147:23-148:2.

- "As indicated by the publication dates in many of the above items, due diligence would have detected all of these mesh defects and helped to predict the complications now known to occur before the introduction of Gynemesh to the medical marketplace. Such adverse events became apparent after patient experimentation paid for by insurance companies." Ex. B, Ostergard Report at 3, ¶ 7(i).

- All of Dr. Ostergard's statements offering a narrative review of Ethicon's corporate documents. *Id.* at 4-8, ¶¶ 9(a)-(nn)); *id.* at 14-18, ¶¶ 10(i)-(t), 11(a)-(v)); *id.* at 22-28. ¶¶ 17(a)-18(tt).

- All of the statements that purport to opine on Ethicon's state of mind, knowledge, motives, or corporate conduct. *Id.* at 4-8, ¶¶ 9(a)-(nn); *id.* at 18-19 ¶¶ 12(a)-(o); *id.* at 19-21, ¶¶ 15(a)-(u); *id.* at 22-28, ¶¶ 17(a)-18(tt).

CONCLUSION

For these reasons stated above, Ethicon asks this Court to grant its Motion to Exclude or Limit the General Causation Testimony of Donald R. Ostergard, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 19, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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